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Comments and Responses Regarding Draft Local Coverage Determination:
Prostate Specific Antigen (PSA)

As an important part of Medicare Local Coverage Determination (LCD) development, National Government Services solicits comments from the provider community and from members of the public who may be affected by or interested in our LCDs. The purpose of the advice and comment process is to gain the expertise and experience of those commenting.

We would like to thank those who suggested changes to the draft Prostate Specific Antigen (PSA) LCD. The official notice period for the final LCD begins on October 1, 2008 and the final determination will become effective on November 15, 2008.

Comment: A commenter was concerned about the duplication of CPT codes between the LCD and the PSA NCD and suggested requesting an update to the NCD by adding CPTs 84152, 84154 and G0103 rather than to create another document.

Response: It is the responsibility of the local contractors to develop LCDs when an NCD is silent on an issue. The LCD does not conflict with the NCD and therefore the presence of these codes do not present a problem. If fact, the LCD does identify the extent of the national coverage.

Comment: Regarding the LCD on PSA: In the "Indications" section, it states "Free PSA is covered when tPSA is in the 2.6-10.0 range, DRE is normal, and there is either a contraindication to biopsy or the patient has had an initial biopsy that was negative."

In the "Limitations" section it states, "Free PSA will be permitted for men with serum PSA levels between 4.0 and 10.0 who are being considered for prostate biopsy."

It looks like two different people wrote these sections, who didn't talk to each other. What level of tPSA is required; 2.6-10.0 or 4.0-10.0? Does there need to be a contraindication for biopsy or not? Does there need to be an abnormal DRE?

The two sections should read the same. I would suggest that if a tPSA is > 4.0, or > 2.6 in younger (<60 years old?), then biopsy will always be "considered," and fPSA will help make the decision, and should be allowed. I don't believe a "contraindication to biopsy" should be included. If the DRE reveals irregularity, then perhaps fPSA would be superfluous, but an enlarged prostate would be an abnormal finding, and fPSA would be especially helpful.

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One factor was not addressed, and that is the frequency of fPSA allowed. After the initial one, I'm not sure serial fPSA is very helpful. We frequently do serial tPSAs to monitor rate of rise, or follow-up after treatment for prostatitis, and with our lab, an elevated tPSA will flex to a fPSA, even though we don't want or need it. Perhaps a limitation of one fPSA per year would be a reasonable inclusion in the policy that would cut down on unnecessary expense.

Response: We appreciate the commenter pointing out the inconsistency in the draft LCD as written. In view of the more recent identification of a 15% incidence of prostate cancer in men with tPSA values between 2.6 and 4.0nmol/L , we agree that the use of free-PSA analysis in younger aged men is appropriate (<60years old). In patients with abnormal DRE the need for biopsy is more likely to be based upon the total PSA and the clinical examination, and the free-PSA is less likely to impact the decision-making process. Nonetheless, those men with only borderline values or in whom prior biopsy may have been negative may benefit from a free-PSA. We will change the LCD accordingly.

We appreciate the commenter's advice to restrict the frequency of the free-PSA. However, there was no literature submitted documenting a relationship between a free-PSA velocity and the diagnosis of prostate cancer, or even indicating that such information would be unique and not duplicative of total-PSA velocities. Consequently, we do not believe that it is possible to restrict the frequency of free-PSA in those patients meeting all other clinical necessity for the performance of this test, except that once a diagnosis of prostate cancer is established, then any subsequent free-PSA testing would be considered medically unnecessary and denied.